B|BRAUN JAN 2 5 2002 K013610

Summary of Safety and Effectiveness Information
[510(k) Summary]

SUBMITTER:	B. Braun Medical Inc. 901 Marcon Boulevard Allentown, PA 18109-9341 (610) 266-0500, ext. 2375 Contact: Sheri L. Musgnung, RA Manager
DEVICE NAME:	Perifix® Safety Epidural Needle
COMMON OR USUAL NAME :	Safety Epidural Cannula
DEVICE CLASSIFICATION:	Class II, 21 CFR 868.5150: Anesthesia conduction needle and 868.5140: Anesthesia Conductin Kit .
PREDICATE DEVICE:	B. Braun Medical Inc. Perican Epidural Cannula, K813179 B. Braun Medical Inc. Perifix Set for Epidural Anesthesia Tuohy Needle / Catheter, K813186 B. Braun Medical Inc. Introcan Safety IV Catheter, K982805.
DESCRIPTION:	The Perifix® Safety Epidural Needle will be available in a 17 Gauge and 18 Gauge size and the usable length of the needle will be 3 ½ inches. The device consists of a safety device mechanism to reduce the risk of needlesticks.
INTENDED USE:	An active needle stick prevention device used by physicians to access the epidural space for the purpose of delivering an anesthetic and/or therapeutic agent or to facilitate placement of an epidural catheter. The needle can be used for single dose administration or in conjunction with the epidural catheter for continuous administration.
SUBSTANTIAL EQUIVALENCE:	The Perifix® Safety Epidural Needle is identical in materials and intended use to B. Braun Medical's premarket notification, Perican Epidural Cannula, K813179 and B. Braun Medical's premarket notification, Perifix Set for Epidural Anesthesia Tuohy Needle/Catheter, K813186. The safety mechanism that is utilized in this device has also been cleared in B. Braun Medical's premarket notification, Introcan Safety IV Catheter, K982805. Functional testing was performed to support that there are no new issues of safety or effectiveness raised by the Perifix® Safety Epidural Needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 5 2002

Ms. Sheri L. Musgnung
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109

Re: K013610
Perifix® Safety Epidural Needle
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II (two)
Product Code: 73 BSP
Dated: October 31, 2001
Received: November 5, 2001

Dear Ms. Musgnung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. In addition, if you wish to change or expand the current indications for use to include non-military environments, you will need to submit a new 510(k) premarket notification, and receive FDA clearance prior to marketing the device.

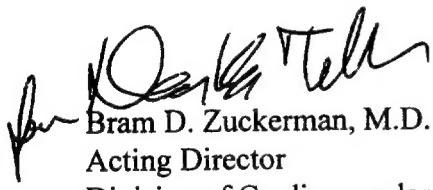
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B|BRAUN

2.0 Indications for Use Statement

510(k) Number (if known): K013610

Device Name: Perifix® Safety Epidural Needle

Indications For Use:

An active needle stick prevention device used by physicians to access the epidural space for the purpose of delivering an anesthetic and/or therapeutic agent or to facilitate placement of an epidural catheter. The needle can be used for single dose administration or in conjunction with the epidural catheter for continuous administration.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013610